EXHIBIT G

MICHAEL R. REED

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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In re Bair Hugger Forced
Air Warming Products
Liability Litigation,

MDL No. 14-2666 (JNE/FLN)

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VIDEOTAPED DEPOSITION OF

MICHAEL R. REED

- -

London, United Kingdom

Taken December 4th, 2016 By Rose Kay

Job No. 115951

APPEARANCES:

THE EXAMINER
Allen Dyer

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I N D E X

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communications about published studies.
MR. GORDON: The communications about published studies relate to criticisms of the published studies and the way to respond to and address those criticisms and why things were or were not done on a particular --
THE EXAMINER: Let's look at the e-mails.
MR. GORDON: That is what we are --
THE EXAMINER: Let's get to the e-mails. I am not persuaded at the moment. If you show me relevant e-mails, I may be persuaded.
MR. GORDON: I will get to it, but you know --
THE EXAMINER: No, I am not going to allow this type of questioning to continue, unless you lay a basis with proper e-mail references to this witness. I am simply not going to allow it to continue.
MR. GORDON: That is fine. I appreciate that Mr. Reed is kind of cutting to the chase and getting things out, that I will get to eventually. So I will stick to the documents. I apologize. This is going to take a little bit longer this way.
BY MR. GORDON:
Q. Let's go to the McGovern paper, and I want to focus on the second part of the study, the comparison or the -- what you described as the clinical component.

A. Yes. I would like to speak to you about that.
THE EXAMINER: Well, let's get to it first, where it is; so that those of us who are not familiar with this document can identify it.
A. So 540.
THE EXAMINER: Yes, I have got that. Where in the document are you talking about?
MR. GORDON: I think the discussion begins on page 543 and it kind of intertwines a little bit, but --
THE EXAMINER: Can I suggest, Mr. Reed, that you allow Mr. Gordon to ask his questions and answer them and then before we leave this document, you can make any point you wish to make about it, unless you think it is essential for you to lay down your marker before you answer questions about it.
A. I would prefer to do that, if that is okay.
THE EXAMINER: Fine. Do it that way.
A. So when I was reading this documentation yesterday and going through e-mails, it's clear to me that some of the data on the clinical side of the paper is wrong, slightly wrong. It doesn't affect the conclusion of the paper and there's still a significant difference. But there is, in fact, one more infection in each group.
Now, this was e-mailed to Mark Albrecht and he did

reply to it and, in fact, it's in your documents; the e-mail correspondence. And he says he will put it into the main paper and, in fact, he then says he has put it in the main paper, but unfortunately it's slightly old data that is in the main paper. It does not affect the conclusion in any way, but nevertheless it is not the latest data they have got in there, and I don't know why that is.
THE EXAMINER: If Mr. Gordon points you to that specific section, then you can identify it for us.
A. I will ...
BY MR. GORDON:
Q. I am sure we will get to those details.
Just broadly speaking, the clinical component of it was a retrospective observation analysis of infection data; is that correct?
A. So I mean, the data is collected prospectively. So it is not that we look back. It is collected live. So it is prospective in that sense, but I would say it is opportunistic, because we had made the change and then we looked to see what happened. The data is prospective.
Q. Was the data being collected -- were the data being collected for purposes of doing this study?

A. No. We collect data routinely and we have a surveillance team, so that is essentially nursing staff, of which I think we had three at that time, whose job it is purely to look at infection rates, if you like.
Q. Okay. So just again, in broadbrush terms. You had and have a body of infection data and what this study did was to look back at a particular time period; is that correct?
A. Well, we collect --
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. We collect the data as we go, if you like, and we have done since probably, I think, 2007/2008.
BY MR. GORDON:
Q. What is the reference on page 533 to --
THE EXAMINER: 543?
BY MR. GORDON:
Q. 543, thank you. For demographic information on relevant risk factors for surgical site infections, SSI, collected for primary hip and knee replacement procedures performed at our hospitals -- hospital during a 2.5-year period starting 1st July, 2008?
MR. ASSAAD: Where are you reading? I am sorry.

THE EXAMINER: At the top of --
MR. GORDON: At the beginning of the text on page --
MR. ASSAAD: Oh, thank you.
THE EXAMINER: Sorry, what was the question arising out of that?
BY MR. GORDON:
Q. What does that refer to?
A. Well, that's essentially the data that we collect on patients as they come in and have a joint replacement.
Q. Did you just start collecting that data on 1st July, 2008?
A. I think that's probably about right, yes. That's when we went to full-time surveillance. We didn't have a surveillance team. We had part-time surveillance. So in England, there's the -- the NHS law is that you have to submit the one quarter every year, one operation infection rates. And we moved to full-time surveillance in that time. So we had a complete handle on infection rates from that point.
Q. And at the end of that 2.5-year period, did you stop collecting data?
A. No. We still collect data.
Q. The 2.5-year period is the -- would be the time period of the McGovern paper; right? That's -- it's just

a finding that what -- the book-ends of the study?
A. Yes.
Q. Okay.
So when you -- at the start date of 1st July, 2008, patients were being warmed with the Bair Hugger; is that correct?
A. Yes.
Q. And at some point, you transitioned over from warming patients with the Bair Hugger to warming them with the Hot Dog; is that correct?
A. Yes.
Q. And at some point, you were fully transitioned and only had -- were only using the Hot Dog?
A. Yes.
Q. Is that correct?
A. Yes.
Q. So there were really three periods in that 2.5 years. The first period being Bair Hugger only; the second period being transition; and the third period being Hot Dog; is that correct?
A. Yes.
Q. What was the period of Hot Dog only use?
A. So that's in the paper. It's from -- it was something like June till -- until the end of December.

Q. Of ...?
THE EXAMINER: Where is this?
A. So this is page 546. And it's the chart which has been written on.
THE EXAMINER: Oh, I see.
BY MR. GORDON:
Q. So June to December 2010?
A. Yes, I think it's June.
MS. ZIMMERMAN: What page was this?
MR. HOLL-ALLEN: 546. This is the table ...
BY MR. GORDON:
Q. Would that be seven months?
A. It feels about right. Six or seven months.
MR. ASSAAD: There's markings on this page. Did you mark ...
THE EXAMINER: I am a bit confused to where the proper lines are, in the light of all these ...
So you used the Bair Hugger from July 2008 to March -- February/March 2010?
A. No. So the -- what's the best way to explain this chart? So if you can try and ignore the scribbles.
THE EXAMINER: Yes, I am trying to.
MR. HOLL-ALLEN: Sir, I am sorry to interrupt. In the plaintiffs' file, there is a clean copy of the same

document.
THE EXAMINER: Thank you. I don't have the plaintiffs' file.
MR. ASSAAD: And I would prefer to use that, because it seems that this document was used during the Albrecht deposition that was taken in October(?) 2016 and I had to have -- these markings could influence the witness's testimony today. So I would rather have a clean copy.
THE EXAMINER: That is another reason. The principal reason is that it's virtually impossible to understand, with all these markings on it.
MR. HOLL-ALLEN: Would you like to use my copy, sir?
THE EXAMINER: No, it is more important that you have it than I do.
BY MR. GORDON:
Q. Well, let's skip that chart. If you go back to page 543 --
MR. ASSAAD: Are you moving on to the ...
MR. GORDON: No, that was the ...
THE EXAMINER: Which one of these is ...?
A. I think --
BY MR. GORDON:
Q. Under "Joint infection data", there is a reference to: a transition of warming -- forced air warming to

THE EXAMINER: Okay.
A. I mean, there is an enormous amount of operations that fall into those groups. You are probably right, but I don't -- I think a coder wouldn't rely on that to say whether it was trauma or not.
BY MR. GORDON:
Q. When you initially saw a printout of data for use in the McGovern study, did you limit it to non-trauma, hip and knee surgeries?
MR. ASSAAD: Objection, misstates the prior testimony. Lack of foundation. He never stated he saw a printout.
THE EXAMINER: You can answer.
A. So normally, the patients you get on here are elective. So there will be some that come on, that are not elective, and then they will be removed by the surveillance team and put -- not actually removed, but put into a different category of joint replacement.
BY MR. GORDON:
Q. When you compiled the data for the McGovern study, did you in any way try to separate the trauma and the non-trauma patients?
MR. ASSAAD: Objection, misstates the prior testimony.
THE EXAMINER: You may answer.
A. I mean, we definitely attempted to do that, because this

database is meant to be just planned cases, just elective cases.
BY MR. GORDON:
Q. Okay. And by --
A. But we do know that other ones get in through coding and then they will be taken out in the sort of data cleaning process.
Q. By this database, you mean the 788 through 1050 -- 1081?
A. So you know, before we would publish, if you like, on infection rates, then we would go through it, we would check every case is as -- you know, every case, whether the infection is trauma or not. You might by chance end up pulling one out, you might not. I am not aware whether we did with this study.
Q. Okay. The data here, on 788 through 1081, as Mr. Dyer pointed out, began on 1st October, 2007. What was your reasoning for commencing the Bair Hugger only period on 1st July, 2008?
A. So my recollection is that we got a full-time surveillance team at that point. So as I said, previously in the U.K. you only have to do a quarter. Actually, you can choose which operation you do. So you might not have full-time surveillance prior to that.
THE EXAMINER: So one operation, one quartile, per annum?

A. Correct. That's the national standard. But we have moved to doing every operation full-time; and that's why we have got that reliable data. So there would be big gaps in the period. If you looked at 2006, you might only have a quarter of the year populated, which would be very unreliable data.
THE EXAMINER: Yes.
BY MR. GORDON:
Q. So I really want to drill down on the timing; and that is critical. I am going to ask you to take a look at volume 2, pages 487 through 490.
A. Okay.
Q. Have you seen this before?
A. I saw it yesterday.
Q. Is that the first time you saw it?
A. I'm not sure.
MR. ASSAAD: I am going to object for lack of foundation for any questions being asked, if he hasn't established foundation. He has written this document -- the authorship of this document --
THE EXAMINER: You have made your objection. Keep objections short.
MR. ASSAAD: Well, I need to put all the objections for the U.S. court.

THE EXAMINER: I know.
MR. GORDON: They are all preserved.
THE EXAMINER: I am familiar with how U.S. attorneys --
MR. ASSAAD: They are --
MR. GORDON: The only objection is: waives form or foundation.
MR. ASSAAD: I am only doing it for trial --
BY MR. GORDON:
Q. Do you know who Julie Gillson is?
A. Yes. Julie Gillson was one of our matrons.
Q. What is a matron?
A. So it is a senior nurse, essentially.
Q. Was she one of the SSI surveillance nurses?
A. No. So Julie is a matron, so the senior nurse within surgery, if you like. Gail Lowdon leads the surgical site infection surveillance team.
Q. And if you look at the front page of this document. At page 71, the very last paragraph, it says during --
THE EXAMINER: Where are you?
BY MR. GORDON:
Q. Page 71. Oh, I am sorry.
THE EXAMINER: 487.
MR. GORDON: 487, thank you. Page 487, the last full paragraph on the page:

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"During the last two quarters of 2008/2009, Northumbria Healthcare NHS Foundation Trust was reporting SSI rates in the combined total of surgeries in the THR/TKR and repair neck of femur between 3.5 percent and 5.7 percent and was regularly receiving letters from the HPA informing the trust of its high outlier status for SSI."

First of all, did I read that correctly?

A. Yes.

MR. ASSAAD: Objection. Move to strike for hearsay.

BY MR. GORDON:

Q. Did --

THE EXAMINER: (Overspeaking.) ... moving on to a question --

MR. ASSAAD: He can't read evidence in, without establishing a foundation. I am saying this is hearsay. He is reading someone else's words into the record. He is basically advocating this point. Objection for hearsay.

BY MR. GORDON:

Q. Do you recall there being a period of time when the Northumbria Healthcare Trust was getting letters from the HPA about SSI rates?

A. Yes.

Q. And what were those -- first of all, what is the HPA?

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A. So the HPA is the Health Protection Agency and they are the group that collate the national database, based on people collecting it locally. So Gail Lowdon who leads our surgical site infection surveillance team, a member of her team will be uploading that information nationally, if you like, to the Health Protection Agency.

The issue with that is that not every trust puts in the data as we have established; and the infection rates that they quote are very low and, in fact, they have -- I mean, the government advisers on infection have publicly written to say that their quotes -- they quote very low infection rates, unrealistically low, because the surveillance system is poor in many trusts?

THE EXAMINER: Do you have a recollection of these letters being received?

A. Yes.

THE EXAMINER: Okay.

BY MR. GORDON:

Q. And what did Northumbria do in response to those letters?

A. So I mean, we have done lots of things, as I think has become clear. We have made loads of changes over a period, a sustained period, to try and reduce the

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infection rates.

Q. Was there any type of a committee or a working group formed?

A. Yes. So there was a surgical site infection prevention committee, which I chair.

Q. And when was that formed?

A. It may actually even be on here. About 2008, maybe even 2007. That sort of timescale.

Q. And that's your independent recollection?

A. Yes.

Q. So the reason I say that is that on page 548, it says that the multiple -- a multi-disciplinary team formed the trust SSI group and the first meeting took place in December 2008.

A. There you go then.

Q. Well, if you --

THE EXAMINER: What is the --

BY MR. GORDON:

Q. If your recollection is different than what is here --

A. Yes, I think that feels right and she would know. What I would say is that we may have been doing stuff before that, before we did a formal meeting, but it would not have been long before that.

Q. And there is a reference in the next paragraph to:

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"The first action point of this meeting was to place a successful bid to appoint two full-time SSI nurses on a 12-month secondment."

MR. ASSAAD: Objection, hearsay.

BY MR. GORDON:

Q. And my question is: was there -- were there full-time SSI nurses prior to whenever this multi-disciplinary group first met?

A. Yes, so the -- the surveillance was done -- I mean, we should probably go back one step.

So we were named in the paper, based on the 2007 data, as having a high infection rate. And after that, we went to full-time surveillance, some time probably in early 2008, but we didn't have the business case and people -- and people formally appointed to those rules. They were being done, I think, by infection control, rather than by a surveillance team. Same methodology.

MR. ASSAAD: I am going to object again to those line of questions. It is not part of the subject matter of the sealed order. It has nothing to do with the studies that he has been performing, that it has been limited to -- by the Senior Master.

THE EXAMINER: He is still in the --

MR. ASSAAD: I mean, we -- well, it really isn't. It is

A. Rarely, but to get to that point, there is a huge number of surgeries normally as well.
Q. And potentially it could cause death?
A. Yes. Well, it does cause death. I mean, there is a definite association with mortality. It reduces your life span.
Q. Do you consider yourself an expert in peri-prosthetic joint infections?
A. Well, in, you know, the view that I have been invited to the international consensus perhaps, and I do speak frequently on it at meetings. I spoke yesterday in Manchester on it. So yes, I speak quite frequently on it.
THE EXAMINER: And my understanding is that it is not that there is a significant percentage or proportion of infections in this surgery. It is because of the severity of the cost to --
A. Exactly. So it is the severity of the complication which is just game changing for most patients. It is a terrible, terrible complication.
BY MR. ASSAAD:
Q. And do you consider yourself an expert with respect to the causation of peri-prosthetic joint infections?
A. I think "expert" is maybe for someone else to judge, but

I do know a lot about it and I have spent a lot of time researching it.
MR. ASSAAD: We need to go off the record, because of the change of CD.
THE VIDEOGRAPHER: This is the end of tape number 2 in the deposition of Michael Reed. Going off the record at 4:44.
(4:44 pm)
(Break taken.)
(4:49 pm)
THE VIDEOGRAPHER: This is the beginning of tape number 3 in the deposition of Michael Reed. Going on the record at 4:48.
BY MR. ASSAAD:
Q. Mr. Reed, we can agree that you need a bacteria to cause a peri-prosthetic joint infection; correct?
A. Yes.
Q. And we can agree that because of the implant, you need very few bacteria to cause a peri-prosthetic joint infection; correct?
A. Correct.
Q. Contrary to a wound infection, where you might need millions; correct?
A. So if you don't have an implant in situ, then you can

have many, many more bacteria on the wound without getting an infection. So yes, it is much more important when you have got an implant.
Q. So an implant is highly susceptible to a bacteria and the cause of a peri-prosthetic joint infection mainly because of biofilm; correct?
A. Yes, so biofilm is a slime that the bacteria produce that protect it from antibiotics and other mechanisms the body might have to rid the infection. So yes, it is very -- it is driven by biofilm, we think, the difficulties in getting rid of the infection.
Q. And you would agree with me that as a result -- strike that.
You would agree with me that most, if not all of the peri-prosthetic joint infections occur when bacteria gets to the implant during the perioperative period; correct?
A. I am not sure we know that. That's -- but that is sort of an accepted philosophy. But I don't think we know that for sure, in actual fact. But that is the dogma.
THE EXAMINER: You referred to the peri ...?
BY MR. ASSAAD:
Q. Peri, during the surgery.
THE EXAMINER: I see, during the operation.

BY MR. ASSAAD:
Q. When you say that is the accepted philosophy, that is the main consensus among most orthopaedic surgeons; correct?
A. Yes.
Q. And because of the biofilm, it is very difficult to treat these peri-prosthetic joint infections through medication; correct, such as antibiotics?
A. Yes. Essentially you can't get rid of an infection with antibiotics alone.
Q. Because there is no vascularity to the joint?
A. Yes, because -- because bacteria and biofilm become very protected by the slime, and so you need about a thousand times the dose of the antibiotic for it to work, and you can't deliver that much antibiotic to the patient.
Q. Have you heard of the term "chain of infection"?
A. Can you -- can you rephrase that?
Q. Yes, I can actually. Basically, for an infection to occur, you have to have an infectious agent, a reservoir, a portal of exit, a mode of transportation, a portal of entry and a susceptible host. Have you heard that described before?
A. Yes.
Q. And for example, so with respect to the infectious

THE EXAMINER: They were at that time?
A. Yes. So this -- briefly, this is a paper where we asked other hospitals around the country that had changed similarly to us, to get in touch; and then we analyzed their data remotely to see what the complications had been.
BY MR. ASSAAD:
Q. And xarelto does not increase increased particles or bacteria to the surgical site; correct?
A. Correct.
Q. I would like you to refer to page 1556.
(Off the record remarks.)
Q. Now, Mr. Reed, you would agree with me that if someone has a peri-prosthetic joint infection, they would have to be returned to the operating room; correct?
A. Almost certainly. Very rarely not.
Q. Okay. So if you look at this document, you have wound complications using xarelto, as compared to a low molecular weight heparin. And then you have, two below it, return to surgery from infection. Do you see that?
A. Yes.
Q. And do you agree with me that if we are looking at PJIs, we should be looking at the differences between xarelto and the low molecular weight heparin for returning to

surgery for infection; correct?
A. Yes, correct. I just have the caveat that I don't know what timescale this looks at. But it is probably within 30 days, which would be a reasonable thing to look at.
(Off the record remarks.)
Q. So would you agree with me that the change from the low molecular weight heparin in the McGovern study to xarelto in the return had no effect; it was not a confounding factor with respect to the infection rates?
A. So based on this study of 12,000 patients, I would say there was no effect on return to surgery from infection.
Q. So would you agree with me that based on this study, that you are an author of, that looking at the date of the McGovern paper, that now we can exclude xarelto as a confounding factor for infection rates?
A. I think that's what this paper says.
THE EXAMINER: Because you nevertheless thought it appropriate to refer to the change in the McGovern paper.
A. Yes, because in our paper, there wasn't a significant difference in infection rates. But there was a signal; that was -- so that's why I put it in. It is safer to be upfront and fair about it.

BY MR. ASSAAD:
Q. And we had a discussion today about the unidirectional airflow in the operating rooms; correct?
A. Yes.
Q. And you believe that it prevents -- using unidirectional flow prevents peri-prosthetic joint infections?
A. Yes.
Q. Because it reduces the particles in the operating room; correct?
A. Yes.
Q. There is an argument that has been made with respect to critiquing your McGovern article, that laminar flow actually increases peri-prosthetic joint infections. Have you heard that argument before, regarding your article?
A. Yes.
Q. And you are of the opinion that, in fact, that needs to be looked at, because you think the forced air warming has an effect on the laminar unidirectional airflow; correct?
A. Yes. I think it may have an effect on that data.
Q. And actually you have written about that in the book chapter published in 2016; correct?
A. Yes, very likely.

Q. We have also discussed keeping patients warm during the preoperative and perioperative period; correct?
A. Yes.
Q. And you believe one or the other is fine; correct? Or I could have misunderstood you.
A. Well, it's not -- you haven't misunderstood me, but I think in terms of where the evidence is, I think that's possibly where the evidence is; one or the other is fine. But I would say the best practice now is to do both. And in fact, the NICE guidance draft, which has just come out, will be to do pre-warming and warming during surgery.
Q. But you agree that there's no evidence, scientific evidence, that indicates that keeping a patient warm during surgery and before surgery reduces peri-prosthetic joint infections?
A. So do -- okay. So there's definitely evidence that in colorectal surgery, that keeping people warm reduces their infection rate. And there is evidence from David Leaper's study, who you are going to meet, that pre-warming patients reduces infection rates in their clean surgery. But that is not during the operation. That is before.
I would say there isn't any evidence that doing